REMARKS

This is a Request for Continued Examination. The claims in this application remaining under examination are 2-10, 12 and 13. In this Preliminary Amendment, claim 13 is amended to meet the rejections of the Examiner. Entry of the amendment is respectfully requested. No new matter is inserted into the application.

Advisory Action

On page 2 of the Advisory Action, the Examiner gives his reasons for maintaining the rejection of claims 2-10, 12 and 13. Applicants respectfully traverse the remaining rejections, and request withdrawal thereof.

First, it appears that the Examiner asserts that the recitation of "sample DNA" in the preamble of claim 13 and then of "a specimen to prepare a double stranded DNA" in lines 11-12 of claim 13 is unclear. The Examiner argues that the phrase "sample DNA" thus refers to two embodiments. Applicants respectfully disagree with the Examiner's interpretation. Nonetheless, in an attempt to resolve this issue, Applicants replace the phase "sample DNA" in the preamble of claim 13 with "double stranded sample DNA prepared by amplification of a particular region of an analyte nucleic acid which is present in a specimen." As such, the "sample

DNA" of the preamble will be phrased in a manner substantially the same as the "sample DNA" referred to in lines 11-12.

Second, the Examiner appears to assert that the fourth paragraph of claim 13, wherein the detection limit is set, is unclear. Again, Applicants respectfully disagree for reasons of record. Contrary to the Examiner's assertions, the method of the present invention does not require "unspecified, active method steps." As recited in the claims, the detection limit for the target DNA present in said sample DNA is A/B, the excessiveness of said sample DNA is at least B/A, and the A/B is the fractional equivalent of the percentage of target DNA content in the sample DNA. Applicants respectfully submit that the setting of the detection limit is clear to those skilled in this technological field, and therefore rejection based upon the above is unfounded.

Third, the Examiner states that the recitation of "rehybridization" in line 24 of claim 13 is confusing since there is allegedly no first recitation of "hybridization." Applicants respectfully disagree. One of skill in the art would understand that before competitive hybridization, the DNA is double-stranded and while the sample is cooled, the DNA "rehybridizes." However, in an attempt to resolve this issue, Applicants amend "rehybridization" in claim 13 to "hybridization."

Applicants respectfully submit that the above amendments and remarks alleviate the Examiner's outstanding rejections such that the present invention is in a condition for allowance. Favorable action and early allowance of the claims are respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at 703/205-8000 in the Washington Metropolitan Area.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: Version with Markings to Show Changes Made

(Rev. 02/12/01)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

The claims have been amended as follows:

Claim 13. (Amended) A nucleic acid assay process for identifying and/or quantifying a mutation or polymorphism in a double stranded sample DNA prepared by amplification of a particular region of an analyte nucleic acid which is present in a specimen, comprising the steps of:

providing labeled standard DNA having a nucleotide sequence the same as a mutated or polymorphic target DNA of interest, wherein said labeled standard DNA comprises a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand;

amplifying said [a] particular region of said [an] analyte nucleic acid which is present in said [a] specimen to prepare said [a] double stranded sample DNA, for competitive hybridization wherein said sample DNA comprises both wild-type and mutated or polymorphic target DNA in an amplifiable amount;

selecting a detection limit for said mutated or polymorphic target DNA, wherein when the detection limit for the target DNA present in said sample DNA is A/B, the excessiveness of said sample

DNA is at least B/A, and wherein A/B is the fractional equivalent of the percentage of target DNA content in the sample DNA;

adding an excessive amount of said sample DNA to said labeled standard DNA, to allow competitive hybridization to take place between said target DNA and labeled standard DNA under conditions which allow for hybridization [rehybridization] of at least some of said labeled standard DNA and under conditions wherein non-target sample DNA does not hybridize with said labeled standard DNA, wherein the excessiveness of said sample DNA added to said labeled standard DNA in the competitive hybridization is selected in accordance with the pre-selected detection limit,

detecting the hybridized [rehybridized] labeled standard DNA by utilizing said detectable label and said site capable of binding to a solid support; and

evaluating the degree of exchange that occurred during competitive hybridization of the complementary strands between said sample DNA and said labeled standard DNA.